A COMPARATIVE EVALUATION OF BOUGIE GUIDED INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY WITH DIGITAL TECHNIQUE IN ADULTS

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CERTIFICATE

This is to certify that the dissertation entitled, "**A COMPARATIVE EVALUATION OF BOUGIE GUIDED INSERTION OF PROSEAL LARYNGEAL MASK AIRWAY WITH DIGITAL TECHNIQUE IN ADULTS"** submitted by Dr.Anand.K , in partial fulfillment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr.M.G.R. Medical University, Chennai is a bonafide record of the work done by him in the Department of Anaesthesiology , Madras Medical College, during the academic year 2005 – 2008.

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CONTENTS

Dr. Archie Brain developed a new way of linking artificial and anatomical airway, between 1981 and 1987. This new concept called Laryngeal Mask Airway combined the advantages of a non-invasive face mask and the more invasive tracheal tube[1].

Originally LMA was recommended as a better alternative to the face mask. But ever since its development the LMA has challenged the assumption that tracheal intubation is the only acceptable way to maintain a clear airway and provide positive pressure ventilation.

Though LMA provided all the above advantages, the risk of gastric distension, pulmonary aspiration of gastric contents and fear of inadequate ventilation acted as a deterrent to the widespread use of LMA.

To overcome the above complications, Dr. Archie Brain designed the Proseal Laryngeal Mask Airway (PLMA) in 2000, with modifications designed to enable separation of gastrointestinal and respiratory tract, improve airway seal, enable positive pressure ventilation and diagnose mask displacement. A Drain Tube (DT) enables diagnosis of mask misplacement, reduces risk of gastric insufflation, regurgitation and aspiration of gastric contents. The PLMA (when placed by the classical digital technique) also posed occasional problems during placement, leading to risk of inadequate ventilation. To overcome these problems, newer placement techniques were described including the thumb placement, Introducer tool placement and GEB (Gum Elastic

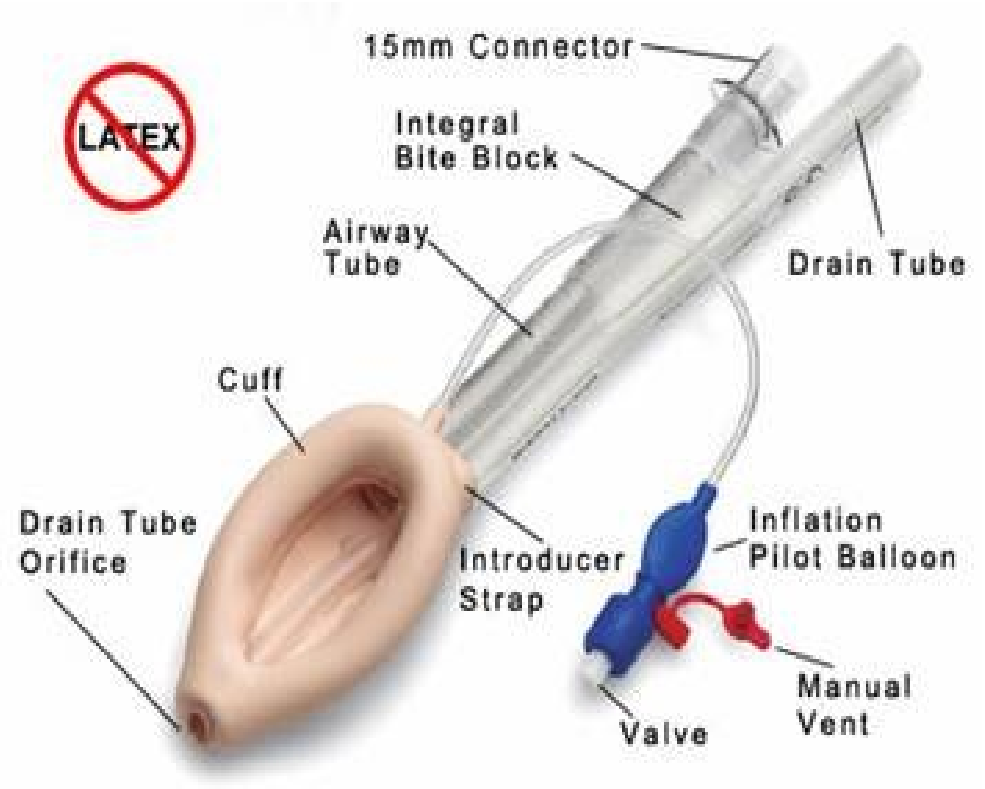
Bougie) aided placement[3,4,6]. All these new techniques touted higher success rates and better placement of the PLMA.

With this background, this study was conceptualized to compare the classical digital placement technique of the PLMA against the GEB aided placement technique

To compare Bougie guided insertion of Proseal Laryngeal Mask Airway (PLMA) with Digital technique in adults with respect to

1. Number of attempts to successful placement.
2. Effective Airway time.
3. Airway trauma during insertion
4. Hemodynamic response to insertion.
5. Postoperative airway morbidity

PROSEAL LMA


15mm Connector
LATEX
Integral
Bite Block
Airway
Tube
Drain Tube
Cuff
Drain Tube
Orifice
Introducer
Strap
Inflation
Pilot Balloon
Manual
Vent
Valve

The Proseal Laryngeal Mask airway (PLMA) was designed and developed by Dr.Archie Brain in late 1990, with a primary goal to construct a laryngeal mask with improved ventilatory characteristics and that also offered protection against regurgitation and gastric insufflation.

DEVICE DESCRIPTION[1]:

The Proseal LMA is made from medical grade silicone and is reusable. It has four main components.

1. Mask
2. Inflation line with pilot balloon.
3. Airway tube
4. Drain tube.

The cuff of the mask has identical proportions but different dimensions amongst sizes.

	MODIFIED FEATURE	INTENDED PURPOSE
1.	The second cuff attached to dorsal surface.	To improve seal by pushing the ventral cuff.
2.	The ventral cuff that is larger proximally	To from a better seal by plugging gaps in the proximal pharynx.
3.	A large conical-shaped distal cuff	To from a better seal with the hypopharynx. To reduce the risk of down folded

		epiglottis obstructing the distal aperture.
4.	A parallel, narrow-bore, double tube configuration	To increase stability. To improve seal by allowing the tongue to from a more effective plug.
5.	A flexible, wire reinforced airway tube	To prevent airway tube from kinking.
6.	A drainage tube	To facilitate gastric tube insertion. To divert regurgitated fluid away from the respiratory tract. To prevent gastric insufflation.
7.	A drainage tube distal aperture that is sloped anteriorly	To allow the deflated tip to form a fine leading edge for insertion.
8.	A plastic supporting ring around the distal drainage tube	To prevent the drainage tube from collapsing when the cuff is inflated.
9.	Drainage tube that passes within the bowl	To avoid altering the external shape of the cuff. To function as mark aperture bar for accessory vent.
10.	A rectangular depression in the proximal bowl tube	To function as an accessory ventilation channel. To prevent pooling of secretion at the distal aperture of the airway.
11.	Built-in-bite block	To prevent airway obstruction.

	To prevent damage to the device during biting. To provide information about depth of insertion. To help fuse airway and drainage tube together.
12. Introducer strap	To prevent finger from slipping off the tube. To keep proximal cuff in the midline.
13. No back plate	To reduce and allow room for the dorsal cuff.
14. No mask aperture bar	To reduce resistance to gas flow.

PROSEAL LMA WITH INTRODUCER TOOL AND CUFF DEFLATOR

INTRODUCER TOOL **7**

The introducer tool is a reusable clip on / clip off device that comprises of a thin, curved, malleable, metal blade with a guiding handle similar to the ILMA. Its inner surface and curved tip are coated with silicone to reduce the risk of trauma. The distal end fits into the locating strap and proximal end clips into the airway tube

above the bite block, with the proximal drainage tube resting to one side.

CUFF - DEFLATOR

It is a dedicated deflation device to aid complete deflation for successful sterilization, optimum insertion and positioning in patients.

SIZES AVAILABLE

Proseal LMA Size	*Patient Selection Guidelines*	*Proseal LMA Airway Tube ID (mm)*	*Maximum Cuff Inflation Volume (Air)*	*Maximum Size*		
				Gastric Tube	*ETT*	*FOB*
1 ½	5-10 Kg	6.4	7 ml	10 Fr	4.5	3.5
2	10-20 Kg	6.4	10 ml	10 Fr	4.5	3.5
2 ½	20-30 Kg	8.0	14 ml	14 Fr	4.5	3.5
3	30-50 Kg	9.0	20 ml	16 Fr	5.0	4.0
4	50-70 Kg	9.0	30 ml	16 Fr	5.0	4.0
5	70-100 Kg	10.0	40 ml	18 Fr	5.0	5.0

These are maximum volumes that should never be exceeded. It is recommended the cuff be inflated to 60cm H_2O intra cuff pressure.

PROTOCOL FOR PLMA USE: **8**

Preparation of Use:

With proper cleaning, sterilization and handling, the Proseal LMA can be safely used 40 times.

Cleaning:

It is washed in warm water and dilute (8-10% w/w) sodium bicarbonate solution until all visible foreign matter is removed. Clean the tubes using a small soft bristle brush. Thoroughly rinse the cuff, airway tube and drain tube in warm, flowing tap water to remove cleaning residues. Care should be taken to ensure that water does not enter the device through the valve.

Sterilization:

Steam autoclaving is the only recommended method for sterilization of the Proseal LMA. Immediately prior to steam autoclaving, deflate the cuff, pulling the syringe backwards to obtain a high vacuum. The maximum temperature should not exceed 135^0C or 275^0F. The Proseal LMA introducer and cuff deflator should be cleaned and sterilized in the same manner.

Performance Tests[1]:

Non-clinical tests must be conducted before each use of the device. These include

1) Visual Inspection:

Ensure that the thin-walled section of the drain tube lying within the mask bowl is not torn or perforated. Do not use the

Proseal LMA if the tubes are discoloured as this impairs the ability to see foreign particles or regurgitated fluids. Examine the surface of the device for damage.

2) Inflation and Deflation:

Using a syringe fully deflate the device so that the cuff walls are tightly flattened against each other. Do not use if the cuff walls re-inflate immediately and spontaneously.

Inflate the cuff from complete vacuum with 50% more air than the recommended maximum inflation volume. Any tendency of the cuff to deflate within 2 minutes indicates the presence of a leak. Examine the symmetry. Inspect the interior of the drain tube.

While the device remains 50% over-inflated examine the inflation pilot balloon for damage.

Pre-Insertion Preparation:

Prior to insertion, the cuff should be fully deflated to a flattened wedge shape. This shape facilities atraumatic insertion and correct positioning in the patient. It reduces the risk of entry of the distal end into the vallecula or glottis and avoids it becoming caught against the epiglottis or the arytenoids.

Methods of cuff deflation includes

- Using original silicone LMA Proseal cuff deflator
- Manually by compressing the distal end between finger and thumb

Lubrication of posterior surface of the cuff with water soluble lubricant like K- Y Jelly should be performed just before insertion to prevent drying of the lubricant.

INSERTION TECHNIQUES

Procedure:

Check the size of Proseal LMA, shape of the cuff and its lubrication. Ideal recommended position for insertion is extension of the head with flexion of the neck (sniffing position).

Insertion Methods[3]:

Having achieved an adequate anaesthetic depth, the device may be inserted using one of the following techniques.

- Using Proseal LMA Introducer
- Using index finger
- Using the thumb
- Using Gum Elastic Bougie

PROSEAL LMA INTRODUCER INSERTION TECHNIQUE[3]

- Place the tip of the Proseal LMA introducer into the retaining strap at the rear of the cuff
- Fold the tubes around the convex surface of the blade.
- Fit the proximal end of the airway tube into the matching slot in the tool.

- Press the tip of the cuff upward against the hard palate and flatten the cuff against it. Slide the cuff further inwards against the palate.

- Jaw may be pushed downwards momentarily to assist against entry between the teeth.

- Keeping the LMA introducer blade close to the chin, rotate the device inwards in one smooth circular movement. During insertion, follow the curve of rigid insertion tool. The jaw should not be held widely open during the movement. Advanced into hypopharynx till definite resistance is felt.

- Before removing the introducer, the non - dominant hand is brought from behind the patients head to stabilize the tube. This prevents the device from being dislodged. It also permits the device to be pushed further inwards, if full insertion has not been achieved by introducer alone.

- Remove the introducer in same circular motion, prior to inflation and fixation of Proseal LMA

INDEX FINGER INSERTION TECHNIQUE[3]

- Finger insertion technique is not recommended for Proseal LMA sizes 1 ½ - 2 ½. These sizes have a dedicated introducer.

- Hold the Proseal LMA like a pen with the index finger pushed into the introducer step.

- Under direct vision, press tip of the cuff upward against the hard palate and flatten the cuff against it.

- As the index finger passes further into the mouth finger, joint begins to extend. The jaws should not be held widely open.

- Push the jaw downwards with middle finger or instruct the assistant to pull lower jaw downwards momentarily using the

index finger to guide the device, press downwards towards the other hand, exerting counter pressure.

- Advance the device into hypopharynx until a definite resistance is felt. Full insertion is not possible unless the index finger is fully extended and wrist is fully flexed.

- Before removing the finger, the non - dominant hand is brought from behind the patient's head to press down on the airway tube. This prevents the device from being pulled out of place when the finger is removed. It also permits completion of insertion in the event that this has not been achieved by the index finger alone. At this point the Proseal LMA should be correctly located with its tip firmly pressed up against the upper oesophageal sphincter. Remove the finger.

THUMB INSERTION TECHNIQUE

- Not recommended for Proseal LMA sizes 1½ - 2½.

- The thumb insertion technique is useful if it is impossible to get access to the patient from behind or to rapidly secure airway while initiating CPR.

- Operator stands facing the patient.

- The thumb is inserted into the strap.

- Insertion is similar to that using the index finger.

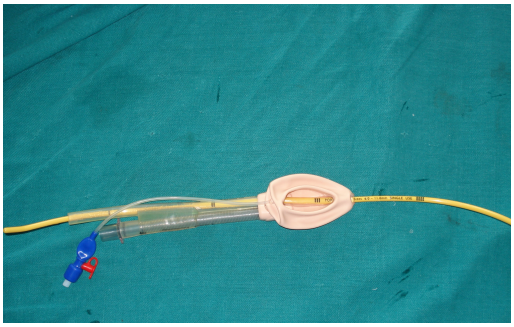
- The thumb should be used to extend the head just prior to completing insertion. This prevents the unopposed backward movement of the thumb causing undesired head flexion.

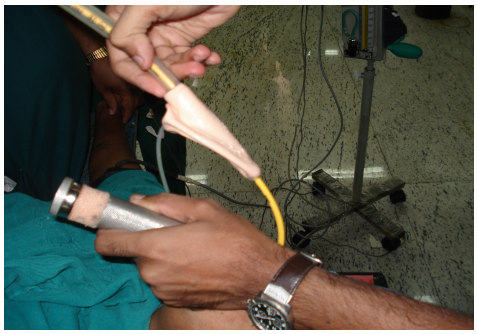
GUM ELASTIC BOUGIE GUIDED INSERTION[3,4,6]:

The Proseal LMA drainage tube is primed with a lubricated, gum elastic bougie with its straight end first and with sufficient length protruding from the proximal drainage tube to grip it.

- The gum elastic bougie is placed in the oesophagus with its straight end first, under gentle laryngoscopic guidance.
- The laryngoscope is removed.
- The Proseal LMA is railroaded along the bougie following the palatopharyngeal curve and using the digital insertion technique.
- The cuff is then inflated and ventilation is commenced.
- The Proseal LMA should be held to prevent dislodgement during removal of gum elastic bougie.
- Alternatively GEB can be placed in oesophagus and the Proseal LMA is threaded over it.
- Alternatively, the laryngoscope can be left insitu and the Proseal inserted under direct vision.

STEPS IN GEB GUIDED PLMA INSERTION





1

2

3

4

5

6

7

8

DEVICEINFLATION: 14

After insertion, the tubes should emerge from the mouth directed caudally. Without holding the tubes, inflate the cuff with just enough air to obtain on intracuff pressure equivalent to approximately 60 cm H_2O. During cuff inflation, do not hold the tube as this prevents the mask from settling into its correct location.

The signs of correct placement may include one or more of the following:

- Slight outward movement of tube upon inflation.
- Presence of smooth oval swelling in the neck around the thyroid and cricoid area.

Never overinflate the cuff.

DEVICE FIXATION:

Once inflated, the device should be fixed in place with fish mouth taping (maxilla to maxilla). While fixing, ensure that the tip of the mask is pressed securely against the upper oesophageal sphincter. Correct fixation is more critical for PLMA because any migration proximally of the tip from hypopharynx will result in air leakage up the DT during IPPV.

PROBLEMS WITH PLMA PLACEMENT & APPROPRIATE CORRECTIVE MANEUVERS:

- An inadequate depth of anesthesia may result in coughing and breath holding during insertion. Should this occur, anaesthesia should be deepened immediately.

- If patient's mouth can not be opened sufficiently to insert the mask, first ensure that the patient is adequately anaesthetized. An assistant can be asked to pull the jaw downward.

- The cuff must press against the palate throughout the insertion maneuver, otherwise the tip may fold back on itself or impact on an irregularity or swelling in the posterior pharynx (e.g. hypertrophied tonsils). If the cuff fails to flatten or begins to curl over as it is advanced, it is necessary to withdraw the mask and reinsert it. If difficulty persists with the chosen technique, then one of the other technique described should be used.

MALPOSITION[2]:

Malposition occurs in approximately 5% to 15% of patients at the first attempt but most occurrences are recognized easily and corrected. Five malpositions have been described, including the following:

1) Distal cuff in laryngopharynx (7%)

2) Distal cuff in glottic inlet (3%)

3) Distal cuff folded over (3.4%)

4) Severe epiglottic downfolding (0.5%)

5) Glottic compression (0.4%)

MANEUVERS TO CORRECT INCORRECT PLACEMENT: 16

a) Cuff in laryngopharynx or glottis:

It occurs when the Proseal is not inserted deeply enough. Pushing the Proseal LMA in further, usually corrects it. Glottic malposition requires reinsertion.

b) Cuff Folded over:

Folding over occurs when the distal cuff impacts against posterior oropharyngeal wall. Techniques to correct this malposition, include

1) Reinsertion using a lateral approach with cuff entering the oropharynx from the side of the hard palate.

2) Reinsertion with the DT stiffened by priming it to the distal end with gum elastic bougie or stylet.

3) Gum elastic bougie guided reinsertion.

4) Digital correction by sweeping a finger behind the cuff.

c) Severe epiglottic downfolding:

This occurs when the epiglottis is dragged inferiorly by the cuff and completely over the glottic inlet. To correct this, Proseal should be reinserted with the head and neck in a more extreme sniffing position, or with jaw thrust applied or with epiglottis lifted through the use of a laryngoscope.

1) Depth of Insertion[12,14]:

It has been observed that when most of the bite block was outside the patient's mouth, Proseal LMA was frequently malpositioned. For women, mean depth of insertion has been found to be 18.6 cm and for men 20.9 cm.

2) Test for obstructed airway:

Unobstructed placement of PLMA is demonstrated by manual ventilation with rise and fall of the chest and square wave capnagraph and normal compliance of reservoir bag.

3) Soap Bubble Test[33,34]:

This is done to evaluate the seal with GIT. Non-toxic soap solution is used to create a membrane over DT tip. Any leak during IPPV will dislodge the membrane.

Uses: 1) Confirms PLMA location behind cricoid cartilage.
2) Confirms zero leak at PLMA - oesophageal seal
3) Detects negative DT pressure and aerophagia with spontaneous ventilation
4) Diagnoses oesophageal insufflation during IPPV.

4) Lubricant Jelly Test:

It evaluates seal with gastrointestinal tract. 0.5 to 1.0 ml of lubricant jelly is placed in the proximal end of the DT to seal it. If there is a leak from the DT, the bolus of jelly is blown off.

5) Suprasternal notch tap test [10]:

This is used to determine whether the leading edge of PLMA lies behind cricoid cartilage. A non toxic soap solution is placed across the proximal end of DT creating a membrane. The suprasternal notch is then gently tapped. A pulsating soap membrane with tapping confirms the tip location behind cricoid cartilage.

6) Gastric tube placement test:

When there is no leak up the DT, then insertion of gastric tube is attempted via DT without using much force. This gives information about the DT patency which is mandatory for safe use of PLMA.

OROGASTRIC TUBE INSERTION:

The primary function of the drain tube is to provide a separate conduit from and to the alimentary tract. This is then passed down the DT of Proseal LMA without any haste or force. A slight resistance is normally felt as the tip passes against upper oesophageal sphincter. There is an inherent resistance to gastric tube insertion after 23 cm of passage due to angulation of 9^0 in the passage of DT to its tip. There may be difficulty in passing gastric tube due to following reasons.

1) Selection of too large gastric tube.

2) Inadequate lubrication.

3) Use of cooled gastric tube.

4) Cuff over inflation.

5) Malposition of PLMA

The advantages of inserting gastric tube are

1) It allows removal of gas or fluid from the stomach

2) Confirms position/patency of drainage tube

3) Functions as a guide to PLMA reinsertion if accidental displacement occurs.

The disadvantages of inserting gastric tube are

1) Risk of tracheal placement

2) Oesophageal perforation rarely

3) The presence of gastric tube may trigger regurgitation by interfering with esophageal sphincter function

4) Gastric tube blocks drainage tube so that gas and fluid cannot escape from oesophagus.

TEST FOR DT AIRLEAK AND PATENCY

Air leak

Large volume leaks are detected by listening over drainage tube or feeling the air with hand. Small volume air leaks are detected best by placing water based lubricant or soap bubble over the end of drain tube.

1) Passage of gastric tube

2) Passage of fibreoptic scope

3) Suprasternal notch tap test[10]

Proseal LMA, a variant of the classic LMA offers certain distinctive advantages. It offers betters seal, better inflation pressure and the ability to decompress the stomach by passing a gastric tube through the drain tube.

Various techniques have been described to achieve optimal placement of PLMA including the introducer tool technique, the index finger technique and the thumb techniques. All these techniques have a learning curve and produce occasional failure. A recently proposed technique utilizes a GEB to aid proper placement of PLMA.

The literature was searched and reviewed to seek the success rate of various insertion techniques and the problems related to these techniques.

1) **M. LOPEZ GIL, J. BRIMACOMBE** et al in 2007[5] compared bougie aided insertion of PLMA Vs Digital technique in 120 children. ASA I & II patients aged between 1-16 yrs were randomly allocated to the digital and bougie guided techniques, where the drain tube was primed with a bougie, and bougie was placed in the oesophagus under direct vision followed by railroading of PLMA. They compared the ease of insertion, number of attempts, efficacy of seal, gastric tube placement, and trauma. The number of attempts for proper placement was lesser in the GEB technique but effective airway time was longer (32 vs 37 secs) All

other parameters were statistically comparable. They concluded that GEB guided insertion of PLMA has a higher first attempt success rate and longer insertion time than digital technique.

2) **HOWATH A, BRIMACOMBE J** et al in 2002[6] determined success rate, cardiovascular responses, and airway morbidity for GEB guided insertion of PLMA. One hundred ASA I / II patients aged 18-80 years were studied. The Proseal LMA drainage tube was primed with well lubricated 16F GEB with straight end protruding 30cm beyond drainage tube. GEB was inserted into oesophagus under laryngoscopic guidance. Laryngoscope was removed and PLMA was inserted using standard insertion techniques with GEB as guide. The following variables were recorded including ease of insertion, oropharyngeal leak pressure, ventilatory capacity, ease of gastric tube insertion, blood staining on bougie or LMA. GEB guided insertion was successful at first attempt in all patients within 50 sec.

   There was no significant increase in heart rate or blood pressure. Oropharyngeal leak pressure was 33 cm H_2O and ventilation was possible without leak in all patients with a TV of 9.5ml / Kg. There were no drainage tube leaks. Gastric tube insertion was successful at first attempt in all patients. Blood staining at removal was not detected on GEB but was detected

in 3% of Proseal LMA. The incidence of sore throat, dysphagia and dysarthria was 21%, 9% and 1% respectively. They concluded that GEB guided insertion of Proseal LMA has high success rate and is associated with minimal hemodynamic change and low incidence of trauma.

3) **BRIMACOMBE J, KELLER C** et al in 2004[7] compared GEB guided insertion of Proseal LMA with introducer tool guided insertion after failed digital insertion. One hundred anaesthetized patients, ASA I/ II aged 18-80 years were randomized for second insertion attempt using either GEB - guided or introducer tool techniques. The bougie guided technique was done as described in above articles. Failed placement was defined as

   - Failed passage into pharynx
   - Malposition
   - Ineffective ventilation.

   Any blood staining was documented. Insertion was more frequently successful (50 vs 15 p=0.002) and faster (35+/-17 vs 34+/-15 sec) with bougie guided technique. Bougie guided insertion has higher success rate and causes less trauma than insertion tool insertion technique after failed digital insertion of PLMA.

4)BRIMACOMBE JOSEPH M.D, KELLER.C et al in 2004[8] compared Digital, Introducer tool (IT) and Gum elastic bougie (GEB) guided techniques for PLMA insertion. The digital and introducer tool techniques were performed according to manufacturer's instruction. The GEB guided technique involved priming drain tube with GEB, placing the GEB in oesophagus under direct vision and inserting Proseal LMA using digital technique with GEB as a guide. Failed insertion was defined by any of the following criteria.

- Failed pharyngeal placement
- Malposition
- Ineffective ventilation.

All other standard data was recorded. They concluded that insertion was more frequently successful with GEB guided technique at the first attempt (G_{100} vsD_{85} vs J_{84}) but success after three attempts (G_{100} vsD_{99} vs J_{98}) was similar. The time taken for successful placement was similar among groups at first attempt but was shorter for GEB technique after three attempts. There was no difference in frequency of visible blood, but occult blood occurred less frequently with GEB guided technique (G_{12} Vs D_{29} Vs I_{31}) but was similar among three techniques if insertion was successful at the first attempt. There was no difference in

postoperative airway morbidity. The authors suggested that GEB technique may be a useful backup technique when digital and IT techniques fail.

5) **GARCIA - AGUADO R, VIOLES J** et al in 2006[9] compared suction catheter guided insertion of Proseal LMA with digital technique. Two hundred and forty three patients (ASA I - III aged 18-84 years) were randomly allocated for digital or suction catheter guided technique. The digital technique was performed according to manufacturer's instructions. The suction catheter technique involved priming the drain tube with suction catheter(SC) so that it protruded by 15cm, and blindly inserting the SC into the pharynx to a depth of 15 cm, followed by digital technique. Failed insertion was defined by any of the following criteria

- Failed passage into pharynx
- Malposition
- Ineffective ventilation.
  All relevant data were recorded.

Fewer insertion attempts (P=0.02) were required with SC - guided technique but overall success rates were similar. The time taken to provide an effective airway was shorter (SC 36 +/- 24 Vs D 44 +/- 28 sec) with the SC guided technique. Lateral approach was required less frequently (SC O% Vs D 4%) for SC –

guided technique. There were no adverse events. Mouth trauma was more frequent with digital technique (P=0.04) but overall trauma was similar. There was no difference in blood staining and postoperative airway morbidity. The authors concluded that suction catheter guided technique is more successful than digital technique and is associated with less mouth trauma during insertion of Proseal LMA.

6) **CORNELIUS J. O' CONNOR JR, CARL.J.BORROMEO, M.D.,** et al., in 2002[10], assessed the efficacy of Suprasternal Notch tap test in confirming accurate position of PLMA tip behind cricoid cartilage. In 50 patients, PLMA was inserted and if necessary reinserted, until satisfactory positioning has been achieved based on following four criteria.

- Inflation of cuff to 60cm H_2O.
- Relation of bite block with respect to incisors.
- Assessment for unobstructed inspiratory and expiratory flow by performing soap bubble test.

In all 50 patients, SSN test has been positive. Hence they concluded positive SSN test reliably indicates the presence of PLMA tip behind cricoid cartilage.

7) **MATTHIAS HOHLREIDER, JOSEPH BRIMACOMBE** et al in 2006[11] compared conventional laryngoscope guided tracheal intubation and laryngoscope guided, GEB aided, Proseal LMA insertion for airway management by first month anaesthesia residents after brief manikin only training. Two hundred ASA I / II anesthetized, paralyzed adult patients were randomly allocated to either of these groups. All relevant data were recorded. Insertion was more frequently successful (100% Vs 65%) and effective airway time was shorter (41±24s Vs 89±625) in PLMA group ($P<0.001$). TV_e was large (730 ± 170ml Vs 560 ± 140ml) and ET CO_2 was lower (33 ± 4 mm Hg Vs 37 ± 5mm Hg) in guided Proseal LMA group. Blood staining was more frequent on laryngoscope (24% Vs 2% $p <0.0001$) in tracheal intubation group. Hence they concluded laryngoscope guided, GEB aided insertion of PLMA was superior to conventional laryngoscope guided tracheal intubation for airway management by first month anaesthesia residents after brief manikin only training.

8) **N.R. EVANS, S.V. GARDNER** et al in 2002[12] assessed insertion characteristics, airway seal pressure, hemodynamic response to insertion, ease of gastric tube placement, gastric insufflation and postoperative sore throat in 300 anaesthetized adults. Insertion was successful in 94% of patients and graded as easy in 91%

of patients. There was no difference in ease of insertion or success rate with either introducer or finger insertion

method. Mean airway pressure was 29cm H_2O and 20% of patients had seal pressures >40cm H_2O. Gastric tube placement was successful in 98.6% of patients. There was no hemodynamic response to insertion. Sore throat was noted in 16% of patients after 24 hours. Hence, they concluded PLMA was a reliable supraglottic airway device that gives an effective seal.

9) KELLER C, JOSEPH BRIMACOMBE in 2000[13] tested the hypothesis that directly measured mucosal pressure and Oropharyngeal Leak Pressure (OLP) are higher for PLMA compared with Classic LMA. 32 anaesthetized, paralyzed patients were randomly allocated to receive either size 4 LMA or PLMA. It was found that directly measured mucosal pressure was similar between both devices for a given cuff volume(<35 cmH2O). OLP was higher for the PLMA at all cuff volumes. Hence, they concluded that PLMA forms a better seal than LMA without any increase in directly measured mucosal pressure.

10) M.S. STIX, C.J.O CONNOR JR in 2003 [14]assessed depth of insertion of PLMA in satisfactorily positioned PLMAs. The study was conducted on 274 patients of either sex. The position of integral bite block was measured in relation to upper incisors. Depth of insertion was scored by dividing integral bite block

into quarters. They found that midway point of bite block was proximal to incisor (within oropharynx) in

78% of women and 92% of men. The standard deviation for depth distribution in women was 0.8 cm and for men was 1.0 cm. Hence the position of integral bite block relative to upper incisor gives valuable information during assessment of PLMA position.

11) **ALEXANDRE LALLO, PIERRE DROLET** in 2007[15] compared PAXpress with Proseal LMA during anaesthesia with positive pressure ventilation. The study was conducted in 100 adult patients randomized to receive either of the device. All relevant data were recorded. Insertion time was longer for PAX than for PLMA (52±44 sec Vs. 34±23 sec P=0.003). Leak pressure was lower while peak inspiratory pressure and $ETCO_2$ valves were higher (P = 0.016, 0.027, 0.04 respectively) with PAX. Blood staining was more frequent on PAX (58% Vs. 19%) than PLMA and dysphagia was more frequent and severe with PAX. Hence they concluded that ventilatory characteristics of PAX are inferior compared to PLMA.

12) **G. NATALINI, M.E. FRANCESCHETTI** et al in 2003[16] compared Proseal LMA with LMA in obese patients. The study was conducted on 60 obese patients randomized to receive mechanical ventilation through PLMA or LMA. Airway cuffs were inflated to 60cm

H_2O controlled ventilation with 10 cm H_2O of PEEP was applied. If leak fraction was > 15%, intra cuff volume was increased. Intra cuff volume needed to be increased in 45%

of patients in LMA group compared to 13% in PLMA group. Leak fraction in PLMA group was 6% which was comparable to tracheal tube. Hence they concluded that PLMA was a better airway device for morbidly obese patients compared to LMA

13) **J. BRIMACOMBE, KELLER C** et al in 2002[17] compared PLMA and LT airway in paralyzed, anaesthetized adult patients undergoing positive pressure ventilation with respect to various ventilatory parameters. They found that first attempt success rates were similar (85% PLMA Vs 87% LT), but after 3 attempts, success rate was higher for PLMA (100% Vs 92% P=0.02) Oropharyngeal leak pressure was larger for PLMA at recommended cuff volume (29±7 Vs 21±6 Cm H_2O). Tidal volume (614 ± 173 ml Vs 456 ± 207 ml P<0.0001) was larger and $ETCO_2$ (33±9 mm Hg PLMA Vs 40±11mm Hg LT) lower for PLMA. Hence they concluded PLMA offered advantages over LT airway in most technical aspects of airway management.

14) **CHRISTIAN KELLER, BRIMACOMBE J** et al in 2000[18] in a randomized, cross-over cadaver study determined whether PLMA prevents aspiration of regurgitated fluid. Mean oesophageal pressure at which

fluid appeared from drain tube was 10cm H_2O. Mean oesophageal (Pressure at which fluid was seen below cuff with PLMA with DT clamped) was 46cm H_2O at 40 ml cuff volume. For PLMA with DT clamped and classic

LMA, fluid appeared simultaneously above and below the cuff at all cuff volumes. Hence they concluded that correctly placed PLMA allows fluid in oesophagus to bypass oropharynx in cadaver model.

15) **N.R. EVANS, S.V. GARDNER** et al in 2002[19] did a study in 103 patients by filling hypopharynx with methyl blue dye introduced down DT once mask was in place. At the end of procedure. FOB was passed down airway tube to observe any dyed saline in bowl of mask. Leakage of saline into bowl of mask occurred in two patients in whom displacement of mask occurred by upper airway events during surgery. In remaining 100 patients, glottis was isolated successfully during surgery. They concluded that a correctly positioned PLMA can isolate airway from the fluid in hypopharynx.

16) **G.NATALINI, GABRIELLA LANZA, ANTONIA ROSANA** et al in 2002[20] compared frequency of air seal and sore throat with LMA - Proseal and classic LMA during laparoscopic surgery. 60 patients were randomized to receive either LMA - Proseal or classic. All relevant data were collected. All

patients were successfully ventilated with assigned LMA. The leak fraction was 7±3 % with LMA and 7±4% with PLMA. The frequency of sore throat was 13% and 10% in patients with LMA and PLMA respectively. Hence they

concluded PLMA and LMA showed similar airtight efficiency during laparoscopy.

17) **P.P. LU, J. BRIMACOMBE, C. YANG** et al in 2002[21] compared Proseal Vs Classic laryngeal mask airway for positive pressure ventilation during laparoscopic cholecystectomy. Eighty anaesthetized patients were randomly allocated for airway management with PLMA or LMA. All ventilatory parameters were recorded. First time insertion success rates were higher for LMA (40/40 Vs 33/40 P=0.02). Seven patients required two attempts with PLMA. Oropharyngeal leak pressure was higher for the PLMA (29 (SD 6) Vs 19 (4) cm H_2O P<0.001). After carboperitoneum, oxygenation was optimal in all patients in both groups, but ventilation was suboptimal more frequently with LMA (8 Vs O, p=0.01). In three of these eight patients ventilation failed, but was subsequently optimal with PLMA. Hence they concluded PLMA is a more effective ventilatory device for laparoscopic cholecystectomy than LMA.

18) **J. ROGER MALTY, MICHAEL BERIAULT** et al in 2002[22] compared Proseal LMA and endotracheal tube

with respect to pulmonary ventilation and gastric distention during laparoscopic cholecystectomy. 109 patients undergoing laparoscopic cholecystectomy were randomized to receive PLMA or ET tube. Ventilatory parameters and gastric distension were noted in both groups. There was no statistically

significant difference in SpO_2/$ETCO_2$ between both groups. Change in gastric distension during surgery was similar in both groups, Hence they concluded correctly placed PLMA or ET tube provided equally effective ventilation without clinically significant gastric distention.

STUDY DESIGN

This study was a randomized, prospective, comparative study.

STUDY SETTING AND POPULATION

After obtaining patient's written informed consent and Institutional Ethical committee clearance, the study was carried out in General Surgery Operation Theatre, Madras Medical College & Government General Hospital, Chennai from March 2007 to July 2007.

The study was conducted in 60 adult patients of either sex, in the age group of 18-80 years belonging to ASA I & II posted for elective minor surgeries at Government General Hospital,Chennai

INCLUSION CRITERIA

- Adults of either Sex
- > 18 Years
- ASA PS I / II
- Modified Mallampati Score I / II

EXCLUSION CRITERIA

- Age < 18 Years
- Obesity
- Pregnancy

- Inter incisor distance < 2cm
- Potential full stomach patients.
- Patients with risk of aspiration like hiatus hernia, reflux oesophagitis, GERD.
- Modified Mallampatti Score 3 & 4
- Pre-existing lung disease

STUDY METHOD

Patients were randomized into 2 groups using the sealed envelope technique.

i. Group D - Digital technique for PLMA insertion

ii. Group G - Gum Elastic Bougie Guided technique for PLMA insertion

All patients were fasted overnight. They were given aspiration prophylaxis with Inj. Ranitidine 50mg IV and Inj. Metoclopromide 10mg IV 1 hour before surgery. Patients were premedicated with Inj. Glycopyrrolate 0.2 mg IV 1 hr before surgery. After the placement of standard minimum monitoring devices [ECG, SpO_2 ,NIBP, Capnography] and preoxygenation, all the patients were induced with Inj.Fentanyl 2 mcg / kg IV, Inj.Lignocaine 1.5 mg/ kg, Inj.Propofol 3 mg / kg I.V. PLMA was inserted with Digital / GEB technique according to the study group.

PLMA was selected as per body weight chart and was inserted using index finger as recommended by manufacturer.

Group G - Gum Elastic Bougie Guided Insertion

This technique involved following steps

i. The Proseal LMA drain tube was primed with well lubricated 16F GEB with straight end protruding 30 cm beyond drain tube.

ii. Under laryngoscopic guidance, distal portion of GEB was placed 5 to 10cm into oesophagus.

iii. The laryngoscope was removed and PLMA was inserted using digital technique while an assistant stabilized proximal end of bougie.

iv. The bougie was removed while PLMA was held in position.

All insertion were performed in sniffing position with cuff fully deflated and using midline approach.

Three attempts were allowed before insertion was considered a failure. Failed insertion was defined by any one of the criteria.

1. Failed passage into pharynx

2. Malposition

    a. Airleak - Oropharynx (Listening over mouth)

- Gastric (Auscultation over epigastrium)

- Drain Tube(Placing lubricant over proximal DT)

b. Negative Suprasternal notch tap test

3. Ineffective Ventilation

a. TVe < 8ml / Kg

b. ET CO_2 > 45 mm Hg

The time between picking up laryngoscope / PLMA and successful placement was recorded. When insertion was successful intracuff pressure was set at 60cm H_2O. Any episode of hypoxia (SPO_2 < 90%) or other adverse events are noted.In the event of a failed insertion of PLMA ,patient was intubated with an endotracheal tube and surgery was allowed to proceed. Oropharyngeal leak pressure was measured after securing the PLMA. Pulse Rate, Blood Pressure, (Systolic, Diastolic, MAP) were recorded prior to insertion and 1 min, 3 min, 5 min, 10 min intervals after insertion, Anaesthesia was maintained with N_2O 2 litres and O_2 1 litre, Isoflurane 1.5% and IPPV using the anaesthesia ventilator in PRVC mode on the Drager Fabius anaesthesia workstation. Peak Inspiratory Pressure was limited to 30 cm H20. TV_e of atleast 8ml / Kg and $ETCO_2$ < 45 mm Hg was maintained.

At the end of procedure. PLMA was removed after recovery criteria were adequately met. Any visible blood staining on PLMA, laryngoscope, bougie was noted down. Mouth, lips, tongue were inspected for evidence of trauma. 38

Patients were interviewed 18-24 hours postoperatively regarding

1. Sore throat (constant pain even without swallowing)
2. Dysphonia (difficulty or pain on speaking)
3. Dysphagia (difficulty or pain on swallowing)

This prospective, randomized, blinded comparative study compared the classical digital insertion technique of PLMA with the GEB guided, laryngoscope aided insertion technique in 60 adult patients undergoing minor surgical procedures under General Anaesthesia.

All data were collected, tabulated and expressed as Mean +/- Standard deviation. Appropriate statistical analysis was conducted using SSPC 13.0 version. All quantitative data were compared using Unpaired student's t test. All qualitative data were compared using Chi square test. P values were calculated for all tests. A p value </= 0.05 was considered significant.

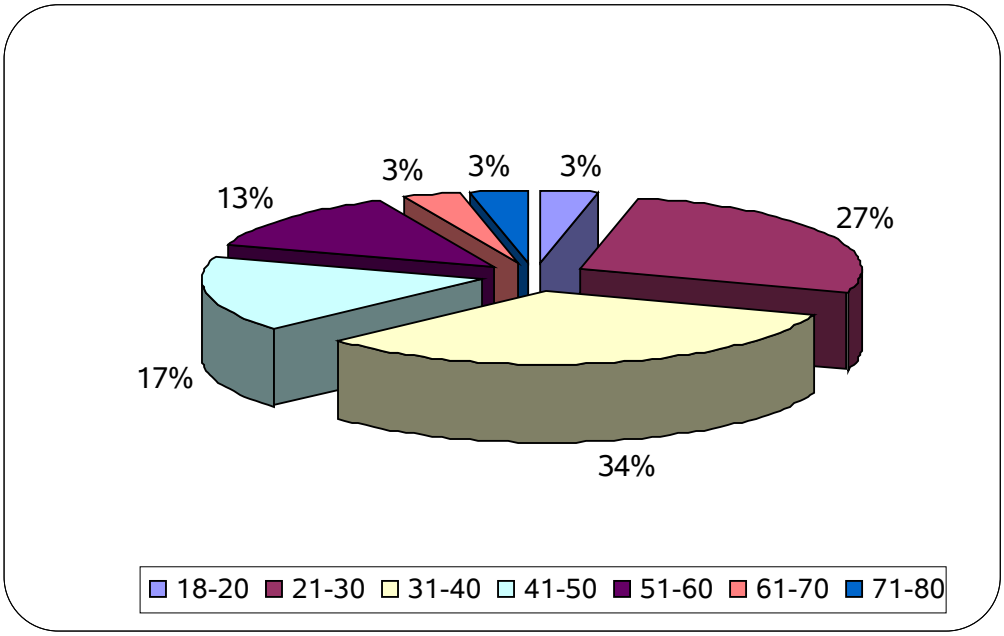
The summated results are presented below

DEMOGRAPHIC DATA:

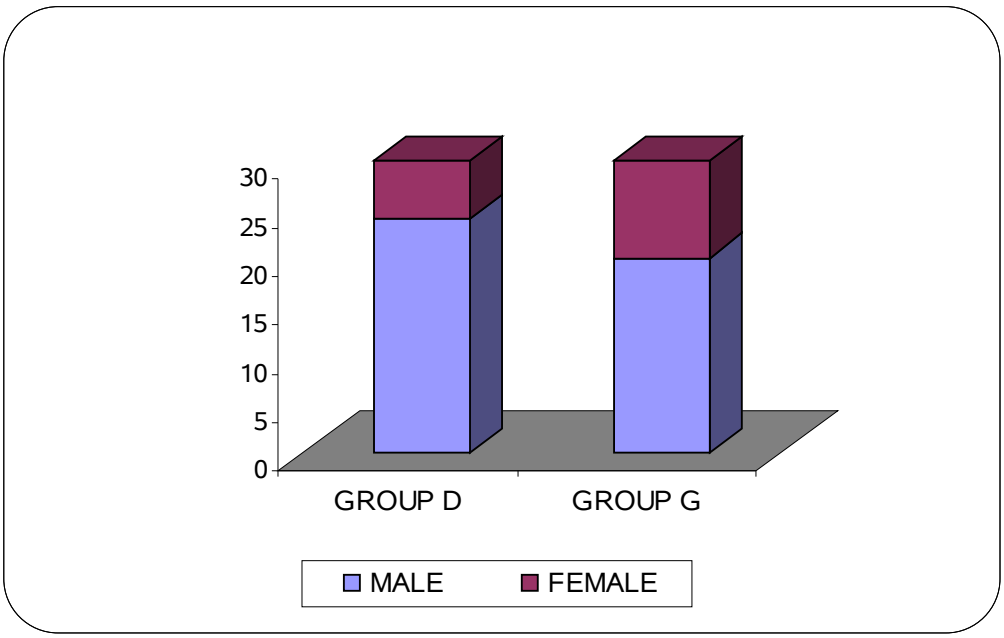
AGE

AGE(YEARS)	GROUP D	GROUP G	
18-20	1	1	$\chi 2$ yates=8.02 P=0.23 Not significant
21-30	8	8	
31-40	10	6	
41-50	5	11	
51-60	4	4	
61-70	1	0	
71-80	1	0	

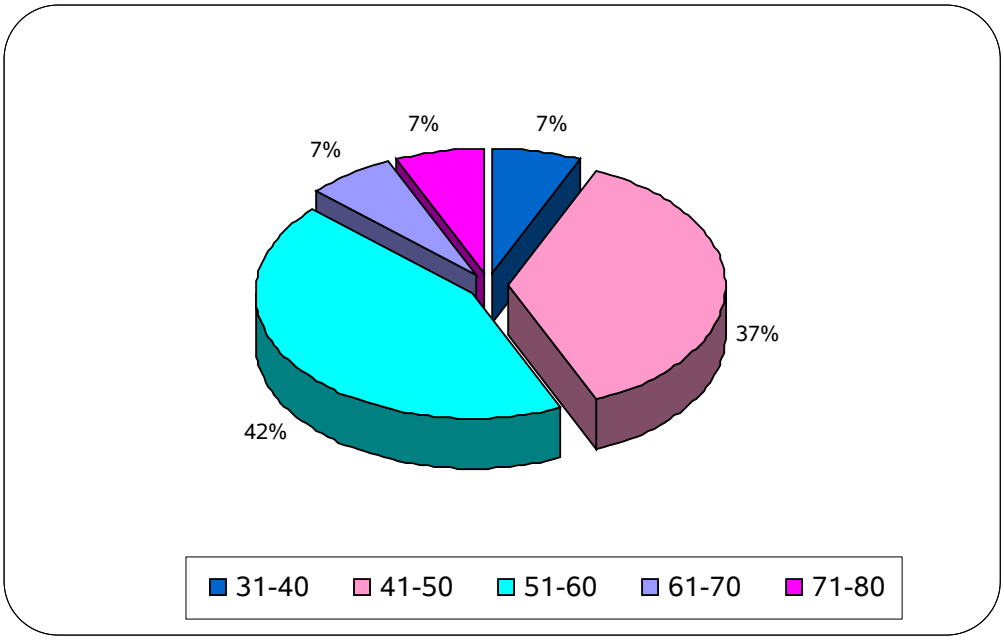
AGE DISTRIBUTION



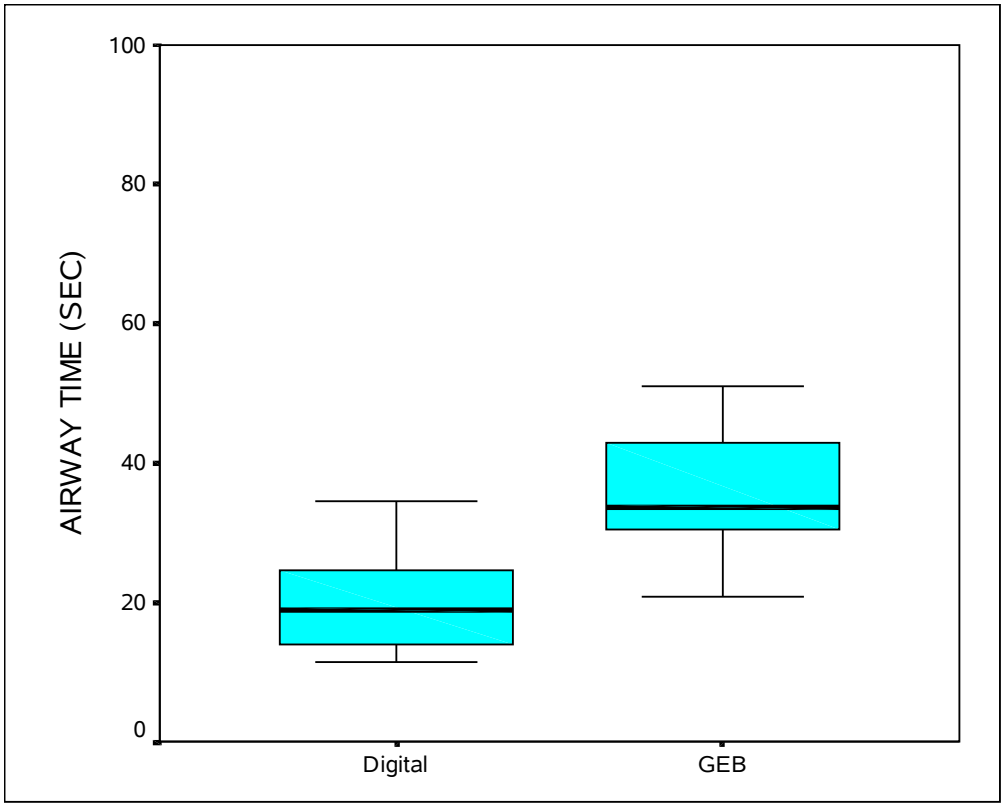
SEX DISTRIBUTION



WEIGHT DISTRIBUTION



EFFECTIVE AIRWAY TIME



SEX	GROUP D	GROUP G	
MALE	24	20	$\chi 2$ yates=1.36 P=0.24 Not significant
FEMALE	6	10	

WEIGHT

WEIGHT	GROUP D	GROUP G	
31-40	2	0	$\chi 2$ yates=5.04 P=0.28 Not significant
41-50	11	8	
51-60	13	13	
61-70	2	6	
71-80	2	3	

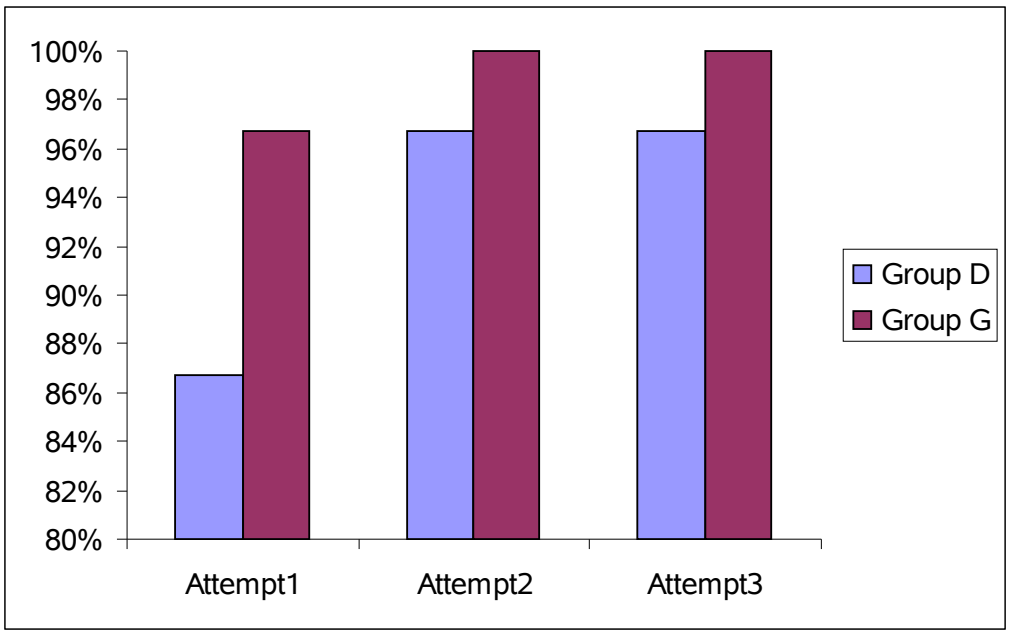
Both the groups are statistically comparable with respect to demographic variables like age, sex and weight

EFFECTIVE AIRWAY TIME

	Group	n	Mean	SD	Student t-test
Airway Time (sec)	D	30	22.327	12.090	t=4.83 P=0.001 Significant
	G	30	36.877	11.21	

The airway time is defined as time taken from taking PLMA /

SUCCESS RATES



Laryngoscope in hand till time taken to obtain effective airway as shown by square wave capnography.

The effective airway time for GEB guided insertion of PLMA was 36.87+/-11.2 secs and that for digital insertion was 22.32+/-12.09 secs.

Student's t test reveals p value of 0.001 which is significant. Hence GEB guided PLMA insertion takes longer time than digital technique for successful placement.

NUMBER OF ATTEMPTS TO SUCCESSFUL PLACEMENT

		Group				
		D		G		
		n	%	n	%	**Significance**
Attempt1	No	4	13.3%	1	3.3%	$\chi 2$ yates= 0.87 P=0.35 not significant
	Yes	26	86.7%	29	96.7%	
Attempt2	No	26	86.7%	29	96.7%	$\chi 2$ yates= 0.87 P=0.35 not significant
	Yes	4	13.3%	1	3.3%	
Attempt3	No	29	96.7	30	100.0%	$\chi 2$ yates= 0.67 P=0.27 not significant
	Yes	1	3.3%	0	0.00%	

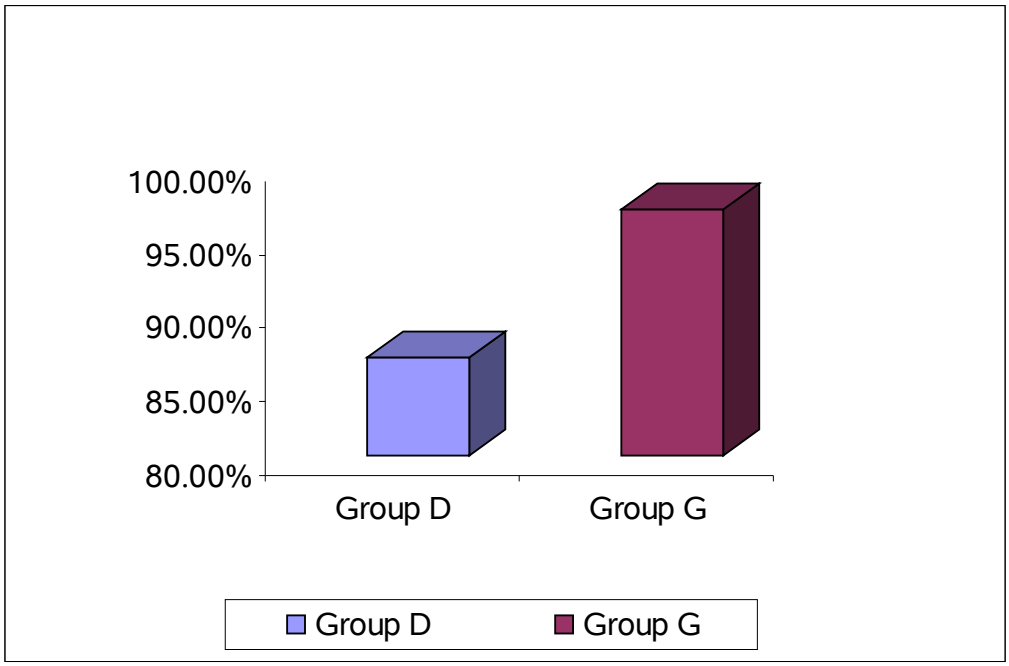
Successful placement of PLMA is defined by the following criteria

i) Square wave pattern on capnography

ii) No airleak over mouth, stomach, drain tube

iii) Positive suprasternal notch tap test

POSITIVE SUPRASTERNAL NOTCH TAP TEST



iv) Effective ventilation (TV_e>8 ml/kg, ETCO2 <45 mmHg) 42

GEB guided PLMA insertion was successful in 29/30 (96.7%) in first attempt, while only one patient 1/30 required second attempt. PLMA insertion with digital technique was successful in 26/30(86.7%) in first attempt and 3/30 (10%) patients required additional second attempt. PLMA insertion failed after three attempts in 1/30 (3.3%) patient in group D.

The difference in successful PLMA placement in two groups, though appearing clinically relevant, on statistical analysis did not reveal any difference.

MALPOSITION

		Group				Significance
		D		G		
		n	%	n	%	
FPP	No	28	93.3%	29	96.7%	$\chi 2$ yates= 0.35 P=0.55 not significant
	Yes	2	6.7%	1	3.3%	
AL O	No	28	93.3%	29	96.7%	$\chi 2$ yates= 0.35 P=0.5 not significant
	Yes	2	6.7%	1	3.3%	
AL G	No	28	93.3%	29	96.7%	$\chi 2$ yates= 0.35 P=0.5 not significant
	Yes	2	6.7%	1	3.3%	
AL D	No	28	93.3%	29	96.7%	$\chi 2$ yates= 0.35 P=0.5 not significant
	Yes	2	6.7%	1	3.3%	
SSN TT	No	4	13.3%	1	3.3%	$\chi 2$ yates= 0.87 P=0.35 not significant
	Yes	26	86.7%	29	96.7%	
IV	No	4	13.3%	1	3.3%	$\chi 2$ yates= 0.17 P=0.35 not significant
	Yes	26	86.7%	29	96.7%	

FPP	Failed passage into pharynx
AL O,G,D	Airleak oropharynx, Gastric, Drain tube
SSN TT	Suprasternal notch tap test
IV	Ineffective ventilation

PLMA malposition is defined as

i) Failed passage into pharynx

ii) Malposition

a) Presence of airleak over Oropharynx, Gastric, Drain tube

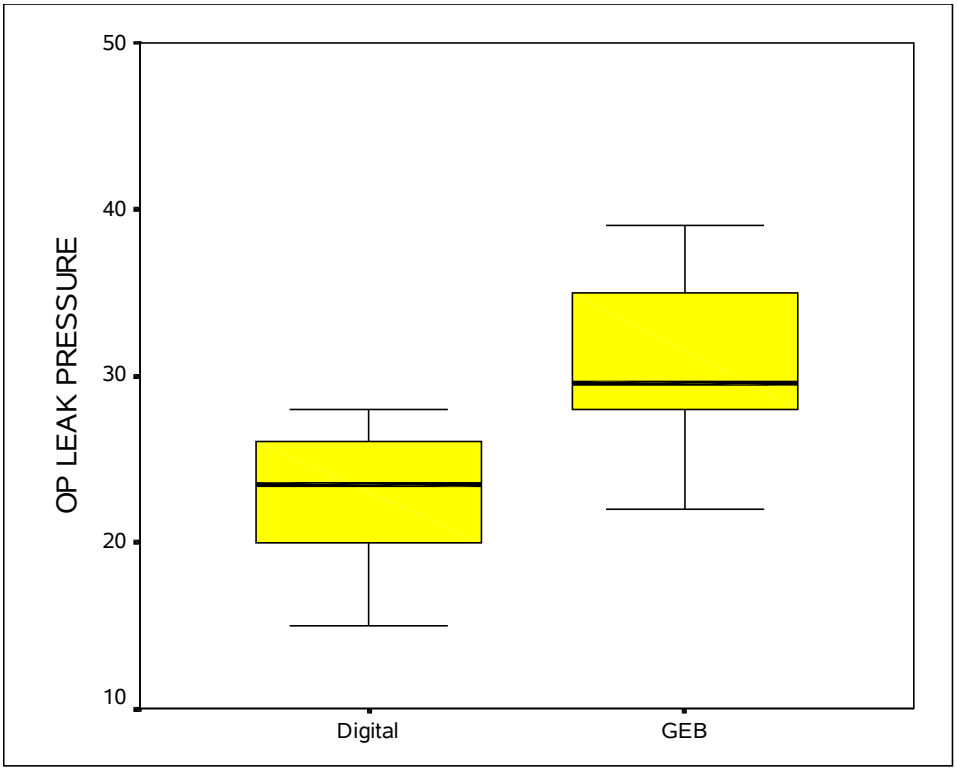
b) Negative Suprasternal notch tap test

iii) Ineffective ventilation (TV_e<8ml/kg, ETCO2>45mmHg)

In GEB guided PLMA insertion, failed passage into pharynx ,airleak over oropharynx , stomach, drain tube, –ve SSN tap test and ineffective ventilation contributed to malposition in 1/30 (3.3%) of cases. In digital insertion of PLMA, failed passage into pharynx, airleak over oropharynx, stomach, drain tube and ineffective ventilation contributed to malposition in 2/30 (6.6%) of patients. Negative SSN tap test contributed to malposition in 3.3% of cases in GEB technique and in 6.6% of cases in digital technique.

GEB guided PLMA insertion seems to be associated with better positioning than digital technique clinically, though statistical analysis do not reveal significant difference.

OP LEAK PRESSURE


OP LEAK PRESSURE
50
40
30
20
10
Digital
GEB

	Group	N	Mean	Std. Deviation	Student t-test
OP LEAK PRESSURE	D	30	23.13	3.693	t=6.86 P=0.001 significant
	G	30	30.63	4.716	

Oropharyngeal leak pressure was measured in the integrated airway monitor in Drager Fabius Anaesthesia machine by gradually increasing tidal volume till airleak was heard over mouth.

Oropharyngeal leak pressure in digital insertion of PLMA was 23.13+/-3.69 mmHg and 30.63+/-4.71 mmHg in GEB guided PLMA insertion.

Student's t test reveals p value of 0.001 which is significant. Hence oropharyngeal leak pressure obtained with GEB technique is significantly higher than digital technique. This indicates that better airway seal was with PLMA inserted by GEB guided technique.

		Group				Significance
		D		G		
		n	%	n	%	
LARYNGOSCOPE	No	NA	NA	30	100.0%	
	Yes	NA	NA	0	0.0%	
PLMA	No	25	83.3%	25	83.3%	χ2yates= 0.00 P=1.00 Not significant
	Yes	5	16.7%	5	16.7%	
GEB	No	NA	NA	29	96.7%	χ2yates= 1.01 P=0.31 Not significant
	Yes	NA	NA	1	3.3%	

In GEB guided PLMA insertion, visible blood staining did not occur over laryngoscope in any of the cases but blood staining on GEB occurred in 1/30(3.3%) of patients. Visible blood staining over PLMA occurred in 5/30(16.7%) of patients in both the groups. Hence there is no difference in incidence of blood staining on PLMA in both groups.

AIRWAY TRAUMA DURING INSERTION

		Group				Significance
		D		G		
		n	%	n	%	
Tongue	No	30	100%	30	100.0%	-
Lips	No	29	96.7%	29	96.7%	χ2 yates= 0.00 P=1.00 Not significant
	Yes	1	3.3%	1	3.3%	
Mouth	No	30	100%	28	93.3%	χ2 yates= 0.51 P=0.47 Not significant
	Yes	0	0.0%	2	6.7%	

Trauma over tongue did not occur in both of the groups while trauma over lips occurred in 1/30(3.3%) of cases in both the groups. Trauma over mouth did not occur in digital technique but occurred

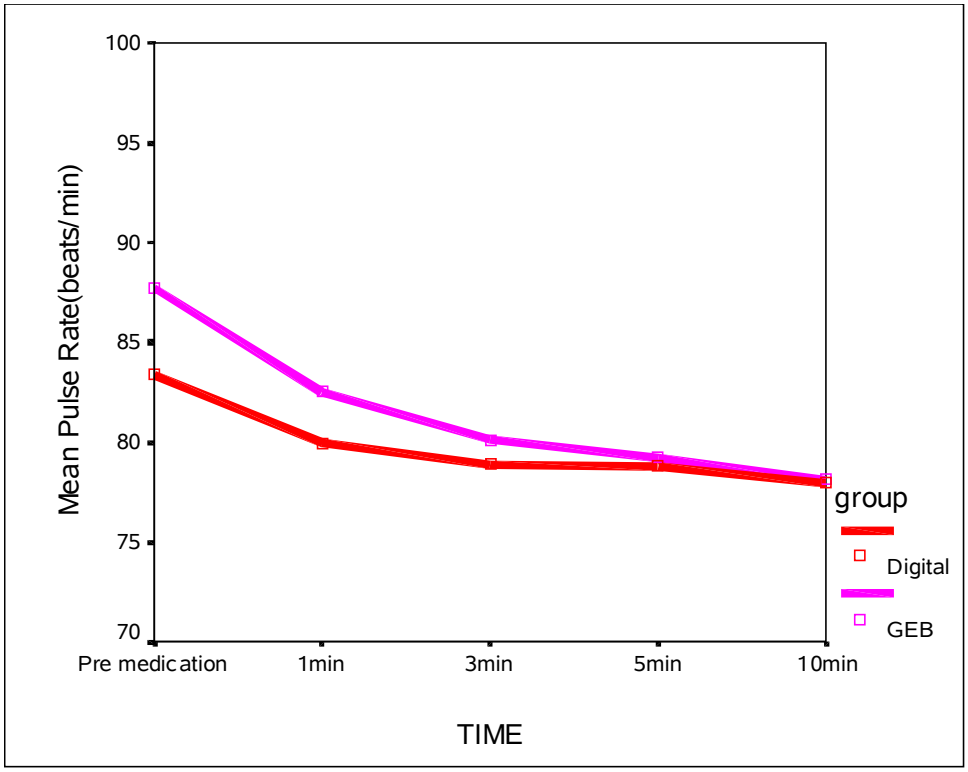
in 2/30(6.7%) of cases in GEB technique. Chi square test reveals p value of 0.47 which is not significant. Hence incidence of airway trauma is same in both the groups.

POST OPERATIVE AIRWAY MORBIDITY

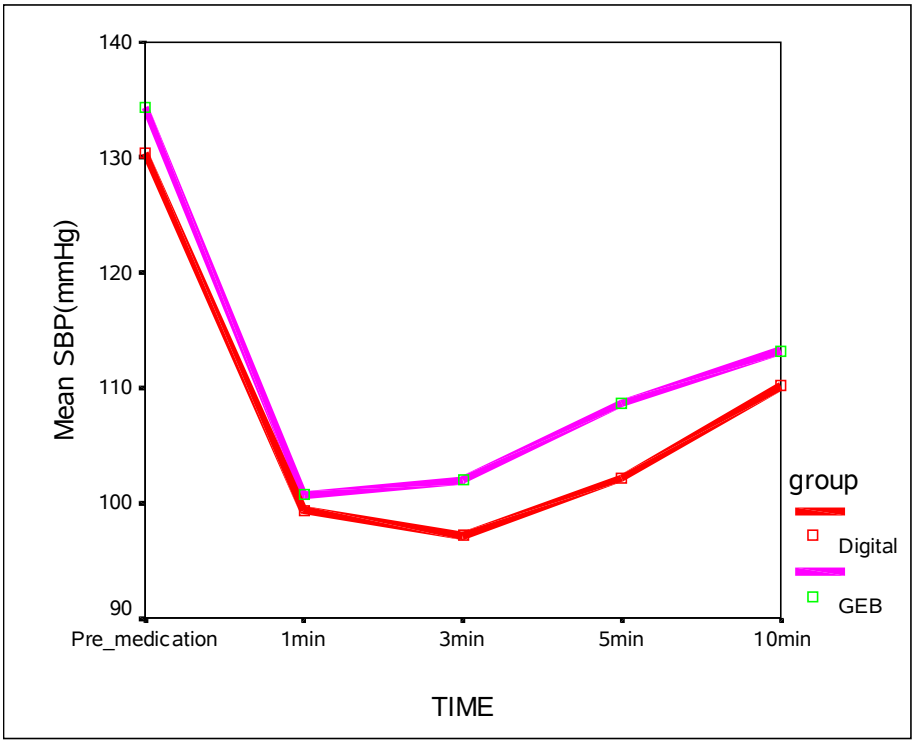
		Group				
		D		G		
		n	%	n	%	Significance
Sore throat	No	27	90%	30	100%	$\chi 2$ yates=1.40
	Yes	3	10%	0	0%	P=0.24 Not significant
Dysphonia	No	30	100%	30	100.0%	-
Dysphagia	No	30	100%	25	83.3%	$\chi 2$ yates = 5.45 P=0.02 significant
	Yes	0	0.00%	5	16.7%	

Post operative sore throat, dysphonia, dysphagia were assessed 18-24 hours postoperatively. Sore throat occurred in 3/30(10%) of patients in digital technique while it was not noted in GEB technique. Dysphagia occurred in 5/30(16.7%) of patients in GEB group while it was not observed in digital technique.

HEART RATE



SYSTOLIC BLOOD PRESSURE



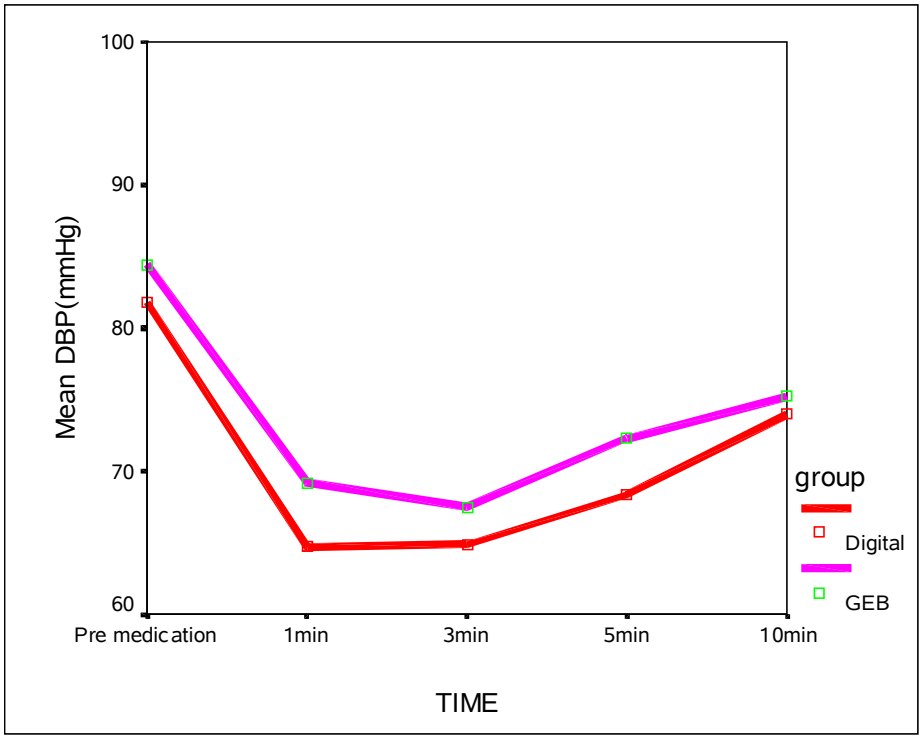
Heart Rate

	Group	n	Mean	SD	Student t-test
HR preinsertion	D	30	83.37	14.583	t=1.07 P=0.29 Not significant
	G	30	87.70	16.670	
HR 1min	D	30	79.93	10.754	t=0.84 P=0.40 Not significant
	G	30	82.50	12.757	
HR 3min	D	30	78.87	11.016	t=0.42 P=0.67 Not significant
	G	30	80.10	11.436	
HR 5min	D	30	78.80	11.845	t=0.15 P=0.88 Not significant
	G	30	79.23	10.566	
HR 10min	D	30	77.93	10.793	t=0.07 P=0.94 Not significant
	G	30	78.13	10.817	

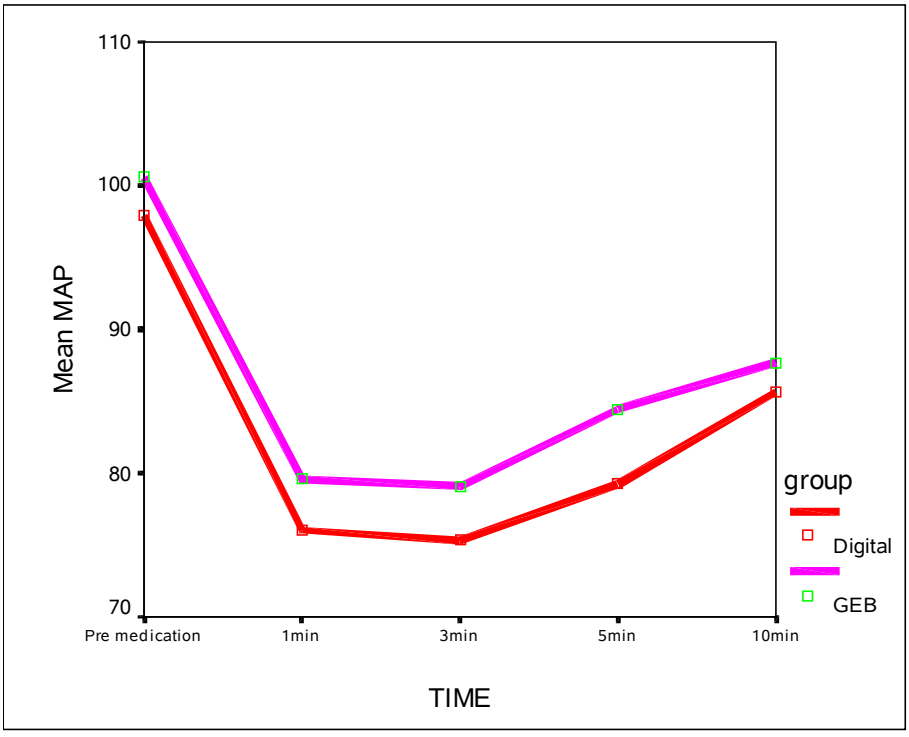
Systolic Blood Pressure (SBP)

	Group	N	Mean	Std. Deviation	Student t-test
SBP Pre	D	30	130.40	15.144	t=0.97 P=0.33 Not significant
	G	30	134.33	16.076	
SBP 1min	D	30	99.33	13.639	t=0.35 P=0.72 Not significant
	G	30	100.67	15.363	
SBP 3min	D	30	97.13	9.804	t=1.52 P=0.13 Not significant
	G	30	102.00	14.532	
SBP 5min	D	30	102.13	11.252	t=1.89 P=0.07 Not significant
	G	30	108.63	15.082	
SBP 10min	D	30	110.13	10.849	t=0.94 P=0.35 Not significant
	G	30	113.23	14.318	

DIASTOLIC BLOOD PRESSURE



MEAN ARTERIAL PRESSURE



Diastolic Blood Pressure(DBP) **48**

	Group	n	Mean	Std. Deviation	Student t-test
DBP Pre	D	30	81.80	9.690	t=1.01 P=0.31 Not significant
	G	30	84.43	10.318	
DBP 1min	D	30	64.70	9.374	t=1.74 P=0.09 Not significant
	G	30	69.20	10.584	
DBP 3min	D	30	64.87	7.655	t=1.04 P=0.30 Not significant
	G	30	67.50	11.524	
DBP 5min	D	30	68.37	7.703	t=1.65 P=0.10 Not significant
	G	30	72.30	10.475	
DBP 10min	D	30	73.97	8.834	t=0.51 P=0.61 Not significant
	G	30	75.23	10.451	

Mean Arterial Pressure(MAP*)*

	Group	n	Mean	Std. Deviation	Student t-test
MAP pre	Digital	30	97.97	11.044	t=0.87 P=0.39 Not significant
	GEB	30	100.57	12.193	
MAP 1min	Digital	30	76.03	10.404	t=1.25 P=0.22 Not significant
	GEB	30	79.57	11.533	
MAP 3min	Digital	30	75.33	7.373	t=1.46 P=0.15 Not significant
	GEB	30	79.07	11.925	
MAP 5min	Digital	30	79.23	8.361	t=1.95 P=0.06 Not significant
	GEB	30	84.43	11.866	
MAP 10min	Digital	30	85.67	9.452	t=0.77 P=0.45 Not significant
	GEB	30	87.70	11.033	

Heart rate, Systolic blood pressure, Diastolic blood pressure, Mean arterial pressure were measured before insertion, 1 min, 3 min, 5 min, 10 min after insertion. The actual values are documented in the tabular column above. Statistical analysis by student's t test reveals p value which is not significant. Hence there is no significant hemodynamic response to PLMA insertion in both techniques.

The Proseal LMA provides an acceptable way to maintain a clear airway & provide positive pressure ventilation. It is also associated with reduced risk of gastric insufflation, regurgitation and aspiration of gastric contents.

Various insertion techniques have been developed by authors to overcome misplaced PLMA leading to ineffective ventilation.

This study was designed to examine two such insertion techniques described for PLMA insertion. In 60 adults undergoing surgical procedures under GA, the classical digital insertion technique was compared with the GEB guided laryngoscope aided insertion technique.

EFFECTIVE AIRWAY TIME

M. LOPEZ GIL, J. BRIMACOMBE et al, in 2005[5] in their study in 120 children studied the effective airway time which was the time from taking the PLMA / Laryngoscope in hand till time taken to obtain an effective airway as shown by a square wave capnography trace. The GEB guided technique required longer time to effective airway (37 Secs VS 32 Secs) . The findings of our study are in concurrence with the above data. The effective airway time for GEB technique was 36.81 $\pm$ 11.21 sec as against time for digital technique of 22.23+/- 12.09 secs.

BRIMACOMBE J, KELLER et al in 2004[7] compared the GEB Vs Introducer tool technique in 100 adult patients. GEB technique had faster effective airway time in comparison to

introducer tool insertion (34± 4.5 secs Vs 35 ± 1.7 sec). The effective airway time in our study was marginally longer (36.81 ± 11.21 Secs) when compared to the above data.

GARCIA AGUADOR, VINOLES J et al in 2004[9] compared effective airway time using two introduction techniques for PLMA. They recorded time of 36 ± 2.4 secs for GEB technique and 44 ± 2.8 Secs for digital techniques. Our study recorded similar time for GEB techniques at 36.81 ± 11.21 Secs. But time recorded with digital insertion was shorter at 22.32 ± 12.09 sec which does not concur with the findings of the above data. Possible reasons for disparity in airway time may be presence of learning curve for a new technique and probably beta error due to small sample size.

NUMBER OF ATTEMPTS TO SUCCESSFUL PLACEMENT

J.BRIMACOMBE , KELLER C et al, in 2004 [8]compared GEB guided insertion of PLMA with that of digital technique in 240 adult patients. They reported higher first attempt success rate with GEB technique (100% vs 88% $p<0.001$). This result is comparable with our first attempt success rate (29/30 vs 26/30 $p=0.035$).

M.LOPEZ GIL, J.BRIMACOMBE et al in 2005[5], in their study in 120 children found that first attempt success rate was higher for GEB guided technique(59/60 vs 52/60 $p=0.015$). This result is comparable with our first attempt success rate (29/30 vs 26/30 $p=.035$)

HOWATH.A, J.BRIMACOMBE, KELLER C et al, in 2002 [6], in their study in 100 paralyzed adult patients found that GEB

guided PLMA insertion was successful in all patients (100/100,100%). This is comparable with our study which reveals higher first attempt success rate (29/30, 96.7%).

J.BRIMACOMBE, KELLER C et al , in 2004[7], compared GEB technique with introducer tool technique in 100 adult patients. They have reported higher success rates with GEB technique than with introducer tool technique (50/50 vs 15/50). This result is comparable with our first attempt success rate (29/30, 96.7%).

MALPOSITION

BRIMCOMBE J, M. LOPEZ-GIL et al in 2005[5] in their study on 120 children compared GEB guided insertion with digital technique. They found that aetiology of malposition with digital technique was oropharyngeal impaction in 3.4% of patients and that of glottic impaction in 10% of patients. The etiology of failed insertion in GEB technique was resistance at the level of hypopharynx in 1/60 patients.

BRIMACOMBE J, KELLER C et al in 2004[8] in their study on 240 adult patients compared PLMA insertion using digital, introducer tool and GEB technique. They found that etiology of failure was failed passage into pharynx in 10% of cases, malposition of PLMA in 8% of cases and failed ventilation in 1% of cases. There were no failed insertions in GEB technique.

In our study etiology of failure was failed passage into pharynx and air leak in 6.7% of cases in digital technique and 3.3% of cases in GEB technique. Ineffective ventilation and Negative

SSN tap test contributed to failure in 13.3% of cases in digital technique and in 3.3% of cases in GEB technique.

OP LEAK PRESSURE

HOWATH A, BRIMACOMBE J, KELLER C et al in their study in 2002[6] , on 100 adult patients found that orophargyngeal leak pressure was 33 cm H_2O with GEB technique. The OP leak pressure measured in our study was 30 cm H2O which is in concurrence with their study.

P.P. LU, J. BRIMACOMBE, C. YANG et al in 2002 [21] in their study of 80 patients concluded that leak pressure with PLMA with digital technique was 29 cm H_2O and that of classic LMA was 19 cm H_2O. In our study the OP leak pressure with digital insertion of PLMA was 23 CM H_2O which is slightly lower than the above mentioned study.

M. LOPEZ GIL, J. BRIMACOMBE et al in 2005[5], in their study on 120 children, found that OP leak pressure was 33 cm H_2O with both digital and bougie guided technique. This does not concur with our study which reveals higher OP leak pressure (30.6 cm H_2O) with GEB technique compared to digital technique(23 cm H_2O).

VISIBLE BLOOD STAINING

BRIMACOMBE JOSEPH, KELLER C et al in 2004[8,] in their study on 240 adult patients, concluded that there was no difference in frequency of visible blood staining on PLMA between digital and GEB guided insertion of PLMA(3/80 vs 2/80). This is in

concurrence with our study which also shows that there is no difference in the incidence of visible blood staining with both techniques (5/30 vs 5/30, 16.7%). The higher incidence of blood staining in both the techniques can be attributed to inexperienced operators.

M. LOPEZ-GIL, J BRIMACOMBE et al in 2005[5] ,in their study on 120 children, concluded that there was no difference in frequency of visible blood staining on PLMA inserted by digital or GEB technique (3/60 Vs 4/60). This is in agreement with our study which also shows no difference in incidence of visible blood staining with both techniques (5/30 Vs 5/30)

HOWATH A, BRIMACOMBE J et al in 2002[6], in their study on 100 adult patients, found that blood staining at removal was not detected on GEB but was detected in 3% of PLMA. This is not in concurrence with our study which shows blood staining in 2% of GEB and in 16.7% of cases on PLMAs. This could be due to inexperienced operators and due to smaller sample size.

AIRWAY TRAUMA

BRIMACOMBE JOSEPH M.D, KELLER C et al in 2004[8], in their study on 240 adult patients found that no patients had mouth or tongue trauma in both groups but two patients had cuts on lips. This is in concurrence with our study which showed that only one patient in both groups (1/30) had trauma on lips. There was no mouth / tongue trauma in both groups in our study.

M. LOPEZ - GIL, J. BRIMACOMBE, L. BARRAGAN et al in 2005[5] , in their study in 2005 in 120 children compared GEB guided insertion of PLMA with that of digital technique. They concluded that 7/60 patients in GEB group had trauma on mouth & lips. This is not in concurrence with our study which reveal only one patient (1/30) had trauma on lips. This could be due to the fact that this study was conducted in children while our study was conducted in adults

POST OPERATIVE AIRWAY MORBIDITY

HOWATH A, BRIMACOMBE J, KELLER et al in 2002[6], in their study on 100 adult patients studied the incidence of postoperative airway morbidity with GEB technique. The incidence of sore throat, dysphagia, and dysarthria was 21%, 19% and 1% respectively. In our study, incidence of dysphagia was 16.7%, while there was no incidence of sore throat or dysphonia.

M.LOPEZ-GIL, J.BRIMACOMBE, L.BARRAGAN et al in 2005[5], in their study on 120 children compared incidence of postoperative airway morbidity with digital /GEB guided insertion of PLMA. They reported dysphonia in 3/60 patients and dysphagia in 1/60 patients in digital technique. The incidence of dysphonia was 1/60 in GEB technique. There was no incidence of sore throat in both the group. In our study, incidence of sore throat was 3/30 in digital group, while the incidence of dysphagia was 5/30 in GEB group, while no patient reported dysphonia in both groups.

HEMODYNAMICS **56**

M.LOPEZ-GIL, J.BRIMACOMBE et al 2005[5], in their study on 120 children found that there was no significant difference

in hemodynamic response to PLMA insertion by digital and GEB technique.

HOWATH A, BRIMACOMBE J, KELLER.C et al in 2002[6], determined success rates, cardiovascular response, airway morbidity for GEB guided insertion of PLMA. They found no significant increases in heart rate or blood pressure during PLMA insertion by GEB technique .

Both these results concur with our findings which found no difference in hemodynamic response to PLMA insertion by either technique.

This prospective, randomized, blinded, comparative study compared the classical digital insertion technique of PLMA with the GEB guided laryngoscope aided PLMA insertion technique in 60 adults undergoing surgical procedures under General Anaesthesia

The following conclusions were deduced from the study

1) The first attempt success rate with digital technique and GEB technique were 86.7% and 96.7% respectively. The success rates after second attempt were comparable (96.7% vs 100%).

2) The effective airway time with GEB (36.87 ± 11.2 sec) was significantly longer than the digital technique (22.32 ± 12.09 sec).

3) Both the techniques had comparable and insignificant incidence of PLMA malposition.

4) The commonest presentation of PLMA malposition was Negative suprasternal notch tap test.

5) Oropharyngeal leak pressure with GEB technique (30.63 ± 4.716mm Hg) was significantly greater than digital technique (23.13 ± 3.693 mm Hg).

6) Blood staining on the PLMA and other airway devices was comparable between the two groups and was not statistically significant.

7) Airway trauma was not statistically different between the two techniques.

8) Sore throat was more frequent with the digital technique while dysphagia was more frequent with the GEB technique.

9) Hemodynamically there was no significant difference between the two insertion techniques with regard to Heart rate, Systolic blood pressure, Diastolic blood pressure and Mean arterial pressure.

Hence, GEB guided laryngoscope aided PLMA insertion is an excellent alternative technique to the classical digital PLMA insertion technique.

The Gum elastic Bougie guided, laryngoscope aided insertion of Proseal Laryngeal Mask Airway is an excellent alternative technique to Digital technique in adults with respect to number of attempts to successful placement, effective airway time, hemodynamic response to insertion, airway trauma and post operative airway morbidity.

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A COMPARATIVE EVALUATION OF BOUGIE GUIDED INSERTION OF PROSEAL LMA WITH DIGITAL TECHNIQUE IN ADULTS.

PATIENT DETAILS:

NAME/IP NO		ASA	
AGE/SEX		COMORBID CONDITIONS	
PROCEDURE		WEIGHT(KG)	

PREMEDICATION:

Glycopyrrolate(0.2 mg)	
Fentanyl (2mcg/kg)	
Lignocaine (1.5mg/kg)	

PREOXYGENATION:

INDUCTION: Propofol (3 mg/kg)

INHALATIONAL ANAESTHETIC: Isoflurane 1.0%

TECHNIQUE EMPLOYED:

DIGITAL	
GEB	

(I)INSERTION DETAILS:

i)Effective Airway time:

ii)No of attempts:

I	II	III

iii)Failed attempts Yes/No

If Yes,

	I I	I II	III
i)Failed passage into pharynx			
ii)Malposition a)Air leak-Oropharynx -Gastric -Drain tube b)Suprasternal notch tap test(+/-)			
iii)Ineffective ventilation TV<8ml/kg, ETCO2>45mmHg			

II)Oropharyngeal leak pressure (mmHg)

III)Hemodynamic parameters:

TIME	BP mmHg SBP/DBP/MAP	HEART RATE

IV) VISIBLE BLOOD STAINING:

	YES/NO
LARYNGOSCOPE	
PLMA	
GEB	

V)AIRWAY TRAUMA:

	YES/NO
TONGUE	
LIPS	
MOUTH	

VI)POST OPERATIVE AIRWAY MORBIDITY:

	YES/NO
SORETHROAT	
DYSPHONIA	
DYSPHAGIA	

VII)ANY OTHER ADVERSE EVENTS:

ABBREVIATIONS

EAT	:	Effective Airway Time.
FPP	:	Failed Passage into Pharynx.
AL O,G,D	:	Airleak Oral,Gastric,Drain tube.
SSN TT	:	Suprasternal Notch Tap Test.
OPL	:	Oropharyngeal Leak Pressure.
VBS	:	Visible Blood Staining.
LAR	:	Laryngoscope.
GEB	:	Gum Elastic Bougie.
PLMA	:	Proseal Laryngeal Mask Airway.
AT T,L,M	:	Airway Trauma, Tongue, Lips, Mouth.
ST	:	Sore Throat.
DPO	:	Dysphonia.
DPA	:	Dysphagia.
HR	:	Heart rate.
SBP	:	Systolic Blood Pressure.
DBP	:	Diastolic Blood Pressure.
MAP	:	Mean Arterial Pressure.
$ETCO_2$	:	Endtidal CO_2
TVe	:	Expired Tidal Volume